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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/038,972	01/04/2002	Jeffrey S. Bartlett	28335/36996US	9566

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EXAMINER	
MARVICH, MARIA	

ART UNIT	PAPER NUMBER
1636	7

DATE MAILED: 10/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/038,972	BARTLETT, JEFFREY S.	
	Examiner	Art Unit	
	Maria B Marvich, PhD	1636	

-- The MAILING DATE of this communication appears on the cover sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-41* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-12, 17-18, 21-26 and 35, drawn to an AAV vector comprising a capsid protein with an amino acid insertion that comprises a targeting peptide, classified in class 424, subclass 199.1.

II. Claims 1-8, 13, 17-19, 21-26 and 35-36, drawn to an AAV vector comprising a capsid protein with an amino acid insertion that comprises an immunogen, classified in class 424, subclass 184.1.

III. Claims 1-8, 14-18, 20, 21-26 and 35, drawn to an AAV vector comprising a capsid protein with an amino acid insertion that comprises a substrate for an enzymatic reaction, classified in class 424, subclass 91.4.

IV. Claims 27-29, drawn to a method of producing AAV vectors comprising a capsid protein with an amino acid insertion classified in class 435, subclass 235.1.

V. Claims 30-34 and 38, drawn to a method of transferring a DNA of interest to a cell, classified in class 435, subclass 471.

VI. Claim 37, drawn to a method for eliciting an immune response in an animal, classified in class 800, subclass 3.

VII. Claims 39-40, drawn to a method of infecting a cell comprising administering an AAV vector to the cell, classified in class 424, subclass 281.1.

VIII. Claim 41, drawn to an AAV vector comprising a biotinylated capsid protein classified in class 424, subclass 1.17.

The inventions are distinct each from the other because of the following reasons:

Group I reads on three patentably distinct DNA constructs comprising one of unrelated SEQ ID numbers 10, 16 and 17. Each sequence is patentably distinct because they are unrelated sequences. Should Group I be elected, Applicants must elect a single sequence for examination. See Examination of Patent Applications Containing Nucleotide Sequences, 1192 O.G. 68 (November 19, 1996) e.g.

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, select to a restriction requirements pursuant to 35 U.S.C. 1121 and CFR 1.141 et seq. Nevertheless, to further aid the biotechnology industry to protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided sua sponte to partially waive the requirements of 37 CFR 1.141 et seq. and permit a reasonable number of such nucleotide sequences to be claimed in a single application.

It has been decided that, due to the high burden placed on the Office to search sequences, ONE sequence constitutes a reasonable number for examination purposes. Applicant is required to elect ONE independent and distinct sequence. Examination will be restricted to only the one elected sequence. This is not a species election. The search of no more than one selected sequences may include the complements of the selected sequence and where appropriate, may include subsequences within the selected sequence (i.e. oligomeric probes and/or primers).

Inventions of Group I -III and Group VIII are directed to products that are distinct both physically and functionally, are not required one for the other and are therefore, patentably distinct. The invention of Group I, drawn to an AAV vector comprising capsids encoding targeting peptides, is physically and functionally distinct from the Invention of Group II, drawn to an AAV vector comprising a capsid encoding an immunogen, from the Invention of Group III, drawn to AAV vectors comprising capsids encoding substrate for an enzymatic reaction, and from the Invention of Group VIII drawn to AAV vectors comprising biotinylated capsids. The peptides of Group I, the immunogens of Group II, the substrates of Group III and the biotinylated capsid proteins of Group VIII are distinct physically. Furthermore, the inventions are functionally distinct. The targeting peptides of Group I direct entry into specific cells while the immunogens of Group II elicit immune response upon binding to antibodies. The substrates of Group III are involved in enzymatic reactions while the biotinylated capsid proteins of Group VIII function as molecular conjugates.

The methods of Group VI are unrelated to the compositions of Group I, Group III and Group VIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the method of Group VI, a method for eliciting an immune response in an animal, does not utilize the AAV vectors of Group I (encoding targeting peptides) nor Group III (encoding substrates) nor Group VIII (encoding biotinylated capsids). Furthermore, the methods of Group VI involve administration of an immunogenic compound to animals to elicit immune response while the AAV vectors of Group I

are used to infect specific cells, while the AAV vectors of Group III are targets of enzymatic modification and the AAV vectors of Group VIII are used to conjugate molecules to the vector.

The compositions of Group I, Group III and Group VIII and the methods of Group IV, V and VII are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05 (h)). In the instant case, the compositions of Group I, Group III and Group III can be used in materially different methods such as for the cloning of heterogenous genes or for nucleic acid hybridization. The compositions of Group II and the methods of Group IV-VII are related as product and process of use. In the instant case, the compositions of Group III can be used in materially different methods such as for the cloning of heterogenous genes or for nucleic acid hybridization.

The methods of Group IV are biologically and functionally different and distinct from the methods of Group V-VII and thus one does not render the other obvious. The methods of Group IV comprise the steps of providing a packaging cell with helper virus function AAV rep gene and a recombinant AAV genome comprising a DNA of interest flanked by AAV inverted repeats for production of AAV virus, which are not required for or are not present in the methods of Group V, VI or VII. The methods of Group IV, therefore, involve the additional techniques for the generation of the recombinant AAV genome with a DNA of interest of introduction of a helper virus for the generation of a packaging cell and growing the cells under conditions in which the AAV vector can be produced. Therefore, the invention of Group IV is a different distinct group capable of supporting a separate patent.

The methods of group VI are biologically and functionally different and distinct from the methods of Groups V or VII and thus one does not render the other obvious. The methods of Group VI comprise the steps of infecting an animal with an AAV vector to elicit an immune response, which steps are not required for or are not present in the methods of Group V or VII. The additional techniques of generating a compound that can induce an immune response and formation of a pharmaceutically acceptable composition and its administration into an animal are not required for the method steps of Group V and VII. Therefore, the inventions of these different distinct groups are capable of supporting separate patents.

The methods of group V are biologically and functionally different and distinct from the methods of Groups VII and thus one does not render the other obvious. The methods of Group V and Group VII both involve administering an AAV vector to a cell. However, the methods of Group V involve the additional steps necessary for the generation of the recombinant AAV genome with a DNA of interest.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provision of MPEP 821.04. Process claims that depend for or otherwise include all the limitations of the patentable produce will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendment submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirements for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 USC 101, 101, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claim in light of *In re Ochiai, In re Brouwer* and 35 USC 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 USC 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP 804.01.

Claims 1-8, 17-18, 21-26 and 35 link the inventions of Groups I-III. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claims. Upon the allowance of the linking claims, the restriction requirement as to the linked inventions shall be withdrawn and any claim depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application. Applicants are advised that if any such claim depending from or including all the limitations of the

allowable linking claims is presented in the continuation or divisional application, the claims of the continuation of divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See MPEP 804.01.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification Group I (424/199.1) vs. group II (424/184.1) vs. Group III (424/235.1) vs. Group IV (435/91.4) vs. Group V (435/471) vs. Group VI (800/3) vs. Group VII (424/284.1) vs. Group VIII (424/1.17), restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter. The searches required for different groups are not coextensive with one another. Therefore, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon cancellation of claims to a non-elected inventions, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B Marvich, PhD whose telephone number is (703) 605-1207. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, Zeta Adams, whose telephone number is (703) 305-3291.

GERRY LEFFERS
PRIMARY EXAMINER

Maria B Marvich, PhD
Examiner
Art Unit 1636